JUN - 9 2000

K001178

microgenics

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K00____.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
phone: (510) 979-5068
fax: (510) 979-5268

Contact: Cynthia Merrell
Manager, Quality Systems

Summary Date: April 6, 2000

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): CEDIA® DAU 6-Acetylmorphine Assay

Name (usual): opiate test system

Classification: 21 CFR 862.3650, Class II, DJG (91)

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

CEDIA® DAU 6-Acetylmorphine Assay is substantially equivalent to CEDIA® DAU Opiate Assay (Microgenics Corporation, Fremont, CA), cleared under premarket notification K935346.

CEDIA® DAU 6-Acetylmorphine Assay is identical or similar to its predicate in terms of: intended use, method principle, device components, risk to the patient, and clinical performance.

Description of Device (21 CFR 807.92 (a)(4))

CEDIA® DAU 6-Acetylmorphine Assay is a two-reagent set intended to be used with automated clinical chemistry analyzers. The assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme ß -galactosidase, which has been genetically engineered into two inactive fragments. These fragments, termed Enzyme Acceptor (EA) and Enzyme Donor (ED) spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the CEDIA DAU 6-AM assay, 6-AM in the sample competes with 6-AM conjugated to ED for antibody binding sites. If 6-AM is present in the sample, it binds to antibody, leaving the ED–6-AM conjugate free to reassociate with EA to form active ß-galactosidase. If no 6-AM is present in the sample, antibody binds to the ED–6-AM conjugate, inhibiting the reassociation of inactive ß-galactosidase fragments, and thus reducing the amount of active enzyme formed. The amount of active enzyme formed, and resulting absorbance change, are proportional to the amount of 6-AM present in the sample. A concentration of 6-AM $\geq$ 10 ng/mL in urine is considered a positive indicator of heroin abuse.

Intended Use (21 CFR 807.92 (a)(5))

The CEDIA® DAU 6-Acetylmorphine Assay is a homogeneous enzyme immunoassay for the in vitro qualitative or semiquantitative determination of 6-Acetylmorphine in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of heroin use or overdose.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between CEDIA® DAU 6-Acetylmorphine Assay and the predicate device follows.

Comparison Table:
CEDIA® DAU 6-Acetylmorphine Assay and CEDIA® DAU Opiate Assay

Device Name	CEDIA® DAU 6-Acetylmorphine Assay (new device)	CEDIA® DAU Opiate Assay (K053315)
Indications for Use	The CEDIA® DAU 6-Acetylmorphine Assay is a homogeneous enzyme immunoassay for the in vitro qualitative or semiquantitative determination of 6-acetylmorphine in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of heroin use or overdose.	The CEDIA® DAU Opiate Assay is a homogeneous enzyme immunoassay for the qualitative and semiquantitative assay of opiates in human urine. Measurements are used in the diagnosis and treatment of opiate use or overdose.
Method Principle	The assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. It is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.	The assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. It is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form a fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.
Components	Enzyme Acceptor Reagent and Enzyme Donor Reagent	Enzyme Acceptor Reagent/Enzyme Acceptor Buffer and Enzyme Donor Reagent/ Enzyme Donor Buffer
Risk to patient	In vitro device, positive results must be confirmed by GC/MS, or other method	In vitro device, positive results must be confirmed by GC/MS, or other method
Clinical Performance	Accuracy: Accuracy against a reference method was 99.5% (189 true positives, 45 true negatives, 1 false negative, close to the cutoff value); Imprecision: Percent CVs across 3 levels of 6-AM concentrations were between 1% and 2%.	Accuracy: Accuracy against a reference method was 100% (100 true positives, 899 true negatives); Imprecision: Percent CVs across 3 levels of opiate concentrations were between 4% and 5%.

Brief Discussion of Nonclinical/Clinical Data (21 CFR 807.92(b)(1, 2))

The CEDIA DAU 6-AM Assay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of precision, linearity, accuracy, and specificity.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as %CVs were below 3% for inter-assay testing, and below 1% for intra-assay testing.

The CEDIA DAU 6-AM Assay is linear between 5 and 20 ng/mL, and also shows good separation in the narrow decision-making range of 7.5 ng/mL to 12.5 ng/mL.

Accuracy studies showed excellent performance of the CEDIA DAU 6-AM Assay as compared to the GC/MS reference method. The clinical sensitivity of the assay was 99.5%, as 189 of 190 6-AM-positive samples were correctly identified. The sole discrepant result was from a sample containing approximately 10 ng/mL by GC/MS (the threshold value). Specificity was 100%, as 46 of 46 6-AM-negative samples were correctly identified.

Specificity testing demonstrated that the CEDIA DAU 6-AM Assay is not affected by common endogenous substances, variations in urinary pH levels, potentially cross-reacting opiates, or various pharmaceutical compounds.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The CEDIA DAU 6-AM Assay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 9 2000

Ms. Cynthia Merrell
Manager, Quality Systems
Microgenics Corporation
46360 Fremont Boulevard
Fremont, California 94538

Re: K001178
Trade Name: CEDIA® DAU 6-Acetylmorphine Assay
Regulatory Class: II
Product Code: DJG, DLJ
Regulatory Class: I
Product Code: JJX
Dated: April 10, 2000
Received: April 11, 2000

Dear Ms. Merrell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): K001178

Device Name: CEDIA® DAU 6-Acetylmorphine Assay

Indications for Use:

The CEDIA® DAU 6-Acetylmorphine Assay is a homogeneous enzyme immunoassay for the in vitro qualitative or semiquantitative determination of 6-acetylmorphine in human urine on automated clinical chemistry analyzers. Measurements are used as an aid in the detection of heroin use or overdose.

Jean Cooper

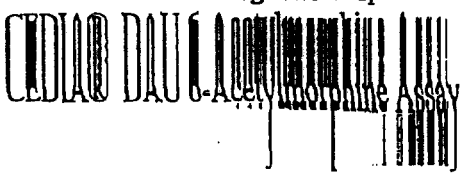
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001178

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)

Microgenics Corporation



Additional Information for K001178

STATEMENT OF INTENDED USE

510(K) Number (if known): K001178

Device Name: CEDIA® DAU 6-Acetylmorphine Calibrator and Controls

Indications for Use:

The CEDIA® DAU 6-Acetylmorphine Calibrator is used to calibrate the CEDIA 6-Acetylmorphine Assay. The CEDIA® DAU 6-Acetylmorphine Controls are used as unassayed control material to validate the calibration of the CEDIA 6-Acetylmorphine Assay.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001178

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)